

Abstracts

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sildenafil. **CONCLUSIONS:** Patients with ED without other relevant concomitant diseases showed better clinical response to treatment than those suffering from associated conditions.

PIH22

LINGUISTIC VALIDATION OF THE MENSTRUAL DISTRESS QUESTIONNAIRE (MDQ) IN AN INTERNATIONAL STUDY FOR A NEW COMBINED ORAL CONTRACEPTIVE PILL

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OBJECTIVES: Prior to use in an international study by NV Organon, the original 48-item menstrual Distress Questionnaire (MDQ), underwent linguistic validation in 26 languages. The original scale was developed in US English to assess the impact of common symptoms and feelings associated with the menstrual cycle. A rigorous methodology was required to ensure conceptual equivalence and cultural relevance across different languages. **METHODS:** The translation process was conducted by a specialist in each target country using the following standardized methodology: 1) two forward translations by professional translators who were native speakers of the target language and fluent in English; 2) comparison and reconciliation of the translations by the specialist in the target country and the translators; 3) back-translation by a native English speaker; 4) comparison of the original and back-translated versions; 5) review by a clinician; 6) comprehension test on 5 women; and 7) review for international comparability. **RESULTS:** The translation process revealed two major challenges. First, the formulation of some original items required the addition of a paraphrase or explanation in some languages. Second, the comprehension tests revealed that in countries where women are less used to completing questionnaires, the instructions asking the respondent to rate the same symptom/feeling for different times during a menstrual cycle were not always understood immediately. This required alternative wording in some translations. **CONCLUSION:** The 26 language versions of the MDQ were established according to a rigorous standardized translation methodology. The process aims to ensure conceptual equivalence across language versions to facilitate international comparison and pooling of data. The linguistic validation process illustrates the value of the integration of international feedback on concepts and wording during the translation of questionnaires.

PIH23

ERECTILE DYSFUNCTION IN SPAIN: CLINICAL RESPONSE TO TREATMENTS

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Erectile dysfunction (ED) is defined as the persistent or recurring incapacity to achieve or maintain sufficient rigidity of the penis to be able to have satisfactory sexual intercourse. **OBJECTIVES:** To determine the clinical evaluation of the treatments prescribed in Spain for ED in terms of efficacy, patient satisfaction, onset of action, tolerability and reproducibility of the effect. **METHODS:** A retrospective epidemiological study was conducted in which we collected demographic data, medical and sexual history, concomitant medication, diagnostic and therapeutic procedures applied to ED and clinical response to the prescribed treatment, in male patients over 18 years of age who had visited a doctor in the 3 months prior to the start of the study. **RESULTS:** Data was collected from 5281 patients. 86.8% of those taking vardenafil obtained an erection that was sufficient

for satisfactory intercourse vs. 59.1% with tadalafil and 45.2% with sildenafil ($p < 0.0001$). The time required to obtain the erection was considered satisfactory in 89.7% of the patients taking vardenafil vs. 65.2% with tadalafil and 44.8% with sildenafil ($p < 0.0001$). The tolerability of the prescribed treatment was satisfactory in 94.3% of the patients who took vardenafil vs. 77.8% with tadalafil and 74.0% with sildenafil ($p < 0.0001$). A total of 85.7% of the patients with ED who took vardenafil referred they were confident that they could obtain and maintain a sufficient erection in each new attempt vs. 57.1% with tadalafil and 44.6% with sildenafil ($p < 0.0001$). The mean prescribed dose of vardenafil was 15.9 mg (SD 5.2), 18.6 mg (SD 6.9) for tadalafil and 60.6 mg (SD 23.7) for sildenafil. **CONCLUSIONS:** Oral treatments for erectile dysfunction provide a good clinical response, observing a statistically higher response with vardenafil at a lower dose.

PIH24

PREFERENCES IN ITALIAN BPH PATIENTS

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OBJECTIVE: To explore the feasibility of producing preferences in the Italian context. **METHODS:** We carried out a pilot experience to assess the preferences of Italian patients (pts) suffering from benign prostatic hyperplasia, using different techniques. Pts expressed their opinions on different scenarios (with/without drugs, TURP). Outcomes to be evaluated were: symptoms relief, risk of urinary retention, adverse events (AEs) etc. Pts were asked to: 1) rank the scenarios according to their preferences; 2) rate (0 to 100) any scenario; and 3) express their Willingness to Pay for each scenario. **RESULTS:** On a sample of 51 pts, the different methods showed similar results except for WTP, whose rationale was difficult to understand by pts. Among preference factors, pts ranked reducing the prostate volume and the risk of surgery at the top of the list; while reducing the risk of urinary retention and avoiding AEs were at the end. Data processing showed an inverse relation between preferences of minimizing AEs and efficacy. **CONCLUSIONS:** We found a lot of difficulties in measuring health preferences. The acceptance to take part into the study was poor. It is likely that the poor acceptance reflects the lack of interest by urologists and pts. Furthermore, the number of published papers on preferences by Italian authors is very scarce. In our opinion, likely explanations of this is that a) in Italy the National Health Service is free/almost free for everybody, and this leads to a difficult evaluation (in economic terms) of a health care intervention; b) scenarios to be evaluated are theoretical, not experienced by pts; c) in a solidarity health service (as the Italian one) the health decision-making is based on political and social basis, and not only on economic analysis; and d) usually the health decisions are based on a quantitative, and not qualitative, approach.

PIH25

THE COUPLE-PROJECT: POOLED ANALYSIS OF SATISFACTION WITH VARDENAFIL TREATMENT IN MEN WITH ERECTILE DYSFUNCTION AND THEIR PARTNERS

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OBJECTIVES: To assess the influence of vardenafil on treatment satisfaction in men with erectile dysfunction (ED) and their female partners. **METHODS:** This was a retrospective pooled analysis of three multicentre, double-blind, flexible-dose, placebo-controlled clinical studies of vardenafil vs. placebo for 12 weeks, in men with ED for at least 6 months duration, and